

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
14 July 2005 (14.07.2005)

PCT

(10) International Publication Number
WO 2005/063803 A1

(51) International Patent Classification⁷: **C07K 14/44**,
C12Q 1/68, G01N 33/569

(21) International Application Number:
PCT/IN2003/000400

(22) International Filing Date:
26 December 2003 (26.12.2003)

(25) Filing Language: English

(26) Publication Language: English

GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (*regional*): ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(71) Applicants (*for all designated States except US*): **ALL INDIA INSTITUTE OF MEDICAL SCIENCES** [IN/IN]; Division of Clinical Microbiology, Dept of Laboratory Medicine, Ansari Nagar, New Delhi 110 029 (IN). **DEPARTMENT OF BIOTECHNOLOGY** [IN/IN]; Ministry of Science & Technology, Block-2, (7th Floor), CGO Complex, Lodi Road, New Delhi 110 003 (IN).

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): **SINGH, Sarman** [IN/IN]; All India Institute of Medical Sciences, Division of Clinical Microbiology, Dept of Laboratory Medicine, Ansari Nagar, New Delhi 110 029 (IN). **SIVAKUMAR, Ramu** [IN/IN]; All India Institute of Medical Sciences, Division of Clinical Microbiology, Dept of Laboratory Medicine, Ansari Nagar, New Delhi 110 029 (IN).

(74) Agents: **LAKSHMIKUMARAN, Varadhachari** et al.; B4/158, Safdarjung Enclave, New Delhi 110 029 (IN).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD,

Declaration under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*

Published:

— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: POLYPEPTIDES FOR THE DIAGNOSIS AND THERAPY OF LEISHMANIASIS

(57) Abstract: The present invention provides compounds and methods for the detection of anti-leishmanial antibodies in individuals suspected of infection with the protozoan parasite of the genus *Leishmania*, where the infectious agent is an Indian strain and similar or closely related to Indian *Leishmania* strains. The compounds provided include polypeptides as shown in SEQ ID NO: 5 or SEQ ID NO: 6 which are useful for the detection of anti-leishmanial antibodies in individuals where the immune responses are elicited against *Leishmania* species of Indian strains and similar or closely related to Indian *Leishmania* strains, the compounds are also useful as a vaccine and therapeutic agent to prevent and treat leishmaniasis. The present invention further provides a diagnostic kit consisting of antibody raised against polypeptides as shown in SEQ ID NO: 5 or SEQ ID NO: 6 for detecting leishmanial antigens.



WO 2005/063803 A1